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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/515,369	02/29/2000	Paul B. Fisher	0575/56778/JPW/JML	1885

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[REDACTED] EXAMINER

SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 06/02/2003

22

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/515,369	FISHER ET AL.	
	Examiner Daniel M Sullivan	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 17 March 2003.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-9 and 14-19 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1,3,4,6-9,14 and 16-20 is/are rejected.

7) Claim(s) 2,5 and 15 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 29 February 2000 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>20</u> .	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

This Office Action is a response to the "Amendment" filed 17 March 2003 (Paper No. 21) in reply to the Non-Final Office Action mailed 10 September 2002 (Paper No. 18). Claims 1-9 and 14-20 were considered and claims 10-13 and 21-25 were withdrawn from consideration in Paper No. 18. Claims 10-13 and 20-25 were canceled and claims 1-5, 8, 9, 14-16 and 19 were amended in Paper No. 21. Claims 1-9 and 14-19 are pending and under consideration herein.

Drawings

The drawings are objected to for the reasons indicated on the attached PTO-948. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

Response to Amendment

Rejection of claim 20 is rendered moot by the cancellation of the claim.

Specification

Objection to the disclosure for reasons of record in Paper No. 18 is withdrawn in view of the amendments thereto.

Claim Objections

Objection to claims 8, 9 and 14-19 for reasons of record in Paper No. 18 is withdrawn in view of the amendments thereto.

Claim Rejections - 35 USC § 112, second paragraph

Rejection of claims 1, 3, 5-9, 15 and 16 under 35 U.S.C. §112, second paragraph, for reasons of record in Paper No. 18 is withdrawn in view of the amendments to the claims.

Claim Rejections - 35 USC § 112, first paragraph

Rejection of claim 16 under 35 U.S.C. §112, first paragraph, for reasons of record in Paper No. 16 is withdrawn in view of the amendment to the claim.

Claims 1, 3, 4, 6-9, 14 and 17-19 stand rejected under 35 U.S.C. §112, first paragraph, as lacking adequate written description for the claimed subject matter for reasons of record in Paper No. 18 and herein below in the “Response to Arguments”.

Claim Rejections - 35 USC § 103

Rejection of claims 1, 3, 6-9, 14 and 17-19 under 35 U.S.C. §103 as obvious over El-Diery *et al.* in view of Jiang *et al.* for reasons of record in Paper No. 18 is withdrawn in view of the amendment of the claims such that they are now limited to a promoter molecule comprising a nucleic acid sequence that is at least 80% identical to the sequence set forth in SEQ ID NO:1. The art of record does not teach or suggest the nucleic acid sequence of the claims.

Response to Arguments

Claims 1, 3, 4, 6-9, 14 and 16-19 were rejected under 35 U.S.C. §112, first paragraph, as lacking adequate written description for a promoter beyond the Mda-7 promoter comprising the sequence set forth as SEQ ID NO:1 (first full paragraph on page 7 of Paper No. 18).

In response to the rejection, Applicant has amended the claims such that they are now limited to an isolated nucleic acid molecules that are at least about 80% identical to the core promoter sequence of SEQ ID NO: 1 and having defined functional characteristics. Applicant

asserts that the specification provides ample support for the functional and structural features set forth in the claims. In particular, Applicant states, “the specification precisely defines the nucleic acid sequence of one embodiment of the *mda-7* promoter (SEQ ID NO: 1), and indicates that other embodiments of the promoter would include those molecules with substantial homology to the *mda-7* sequence of SEQ ID NO: 7 provided that they retain the critical functional characteristics of the *mda-7* promoter” (page 14). Because SEQ ID NO: 7 is a short oligonucleotide that is not disclosed as having functional characteristics of the *mda-7* promoter, it has been assumed that the reference to SEQ ID NO: 7 is a typographical error and should be SEQ ID NO: 1.

These arguments have been fully considered but are not found persuasive because, although the claims are limited to a defined structure and function, the disclosure provides no correlation between the structure and function to which the claims are limited. The promoter of the claims is generic to a structurally diverse set of nucleic acids comprising a sequence at least about 80% identical to the core *mda-7* core promoter sequence. The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species, by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics (see MPEP 2163 (ii)). Applicant has provided a detailed description of a single species having both the structural and functional characteristics of the claimed promoter. The Guidelines for Written Description state, “when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus”, “In an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within

the genus" (Federal Register, Vol. 66, No. 4, Column 2, page 71436). Therefore, the disclosed species clearly fails to adequately describe the claimed genus.

With regard to relevant identifying characteristics, the Guidelines for written description provide that claimed subject matter identified by structural and functional limitations must be supported by a known or disclosed correlation between function and structure (*Id.* at page 1106, column 1, second full paragraph and column 3, second full paragraph). In the instant case, the skilled artisan would not expect that all nucleic acid sequences that meet the structural limitations of the claims would have the recited function, and it would not be apparent from the teachings of the specification and prior art which of the nucleic acids encompassed by the structural limitations would also have the functional characteristics of the claimed promoter. In view of these considerations, and the argument of record in Paper No. 18, a skilled artisan would not have viewed the teachings of the specification as sufficient to show that the applicant was in possession of the claimed invention commensurate to its scope because it does not provide adequate written description for the broad class of nucleic acid molecules encompassed by the promoter of the claims. Therefore, only the described nucleic acid comprising the core promoter sequence of SEQ ID NO: 1 meet the written description provision of 35 U.S.C. §112, first paragraph.

Allowable Subject Matter

Claims 2, 5 and 15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Application/Control Number: 09/515,369
Art Unit: 1636

Page 8

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May 29, 2003


JAMES KETTER
PRIMARY EXAMINER